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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,855	10/27/2003	Tuula Ryde	029318-0988	9261

22428 7590 10/20/2005

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EXAMINER	
GEORGE, KONATA M	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/692,855	RYDE ET AL.	
	Examiner	Art Unit	
	Konata M. George	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *136-189* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *136-189* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 136-189 are pending in this application.

Drawings

1. The drawing(s) filed under 37 CFR 1.184 or 1.152 are accepted by the examiner.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on April 27, 2004; June 22, 2004; September 20, 2004 and December 15, 2004 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Claim Objections

3. Claims 140, 141, 143, 148 and 150 contain the trademark/trade name TRICOR®. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade

name is used to identify/describe 160 mg tablet or 200 mg microcrystalline fenofibrate and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 136-189 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition containing fenofibrate, hypromellose and dioctyl sodium sulfosuccinate in the ratios and amounts as specified in the applicants' examples, does not reasonably provide enablement for all fenofibrate having a particle size of less that about 2000 nm. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The prior art discloses a composition comprising a fenofibrate having the same claimed particles size together with phospholipids.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 136, 137, 163, 164, 167-171, 173, 184 and 185 are rejected under 35 U.S.C. 102(b) as being anticipated by Pace et al. (US 6,696,084).

Pace et al. discloses compositions comprising a fibrate compound. Column 18, lines 46-48 teach a process for the preparation of dried small particles of fenofibrate stabilized by phospholipid. Column 38, lines 14-19 teach the particles size as being in the range of 0.1 micron (100nm) to 2 micrometers (2000nm). Column 16, lines 56-65 teach that the composition of the claimed invention eliminates the difference in the amount of drug taken up when the patient is in a fasting state or in a fed state. Column 17, lines 53-55 teach that the solid fenofibrate may be amorphous, crystalline or a combination of both. Column 1, lines 14-15 teach the composition in the form of tablets, capsules, powders, granules, and dispersions for oral administration. Column 34, lines 3-7 teach that excipients or carriers may be incorporated into the invention. The recitation of functional description of some "additional" property for a compound or a composition containing the same in a dependent claim must result in a tangible structural difference between the product of the independent claim and the product set forth in the dependent claim. Claim 136 is directed towards a composition, which comprises particles of fenofibrate or a salt thereof having an effective particle size of less than about 2000 nm. The Patent and Trademark Office Board of Patent Appeals and Interferences found in *Ex Parte Gray*, 10 USPQ2d 1922, (Bd. Pat. App. And Int. 1989): "Patent and Trademark Office does not have facilities for examining and comparing applicants' claimed human growth factor, which is product-by-process

claims, with prior art, and thus applicants had burden or persuasion to make some comparison between materials in order to establish unexpected properties for claimed factor...Applicant can be required to prove that prior art products do not necessarily or inherently possess characteristics of claimed products...". Gray, Ex Parte, 10 USPQ2d 1922, (Bd. Pat. App. And Int. 1989) 716.01(c), 716.02(g), 2113, 2144.04.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 149-162 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pace et al. (US 6,696,084).

Pace et al. discloses compositions comprising a fibrate compound. Column 18, lines 46-48 teach a process for the preparation of dried small particles of fenofibrate stabilized by phospholipid. Column 38, lines 14-19 teach the particles size as being in the range of 0.1 micron (100nm) to 2 micrometers (2000nm). Column 16, lines 56-65 teach that the composition of the claimed invention eliminates the difference in the amount of drug taken up when the patient is in a fasting state or in a fed state. Column 17, lines 53-55 teach that the solid fenofibrate may be amorphous, crystalline or a combination of both. Column 1, lines 14-15 teach the composition in the form of tablets, capsules, powders, granules, and dispersions for oral administration. Column 34, lines

3-7 teach that excipients or carriers may be incorporated into the invention. The prior art does not teach the claimed concentrations.

With respect to the claimed concentrations, absent a clear showing of critically, the determination of particular concentrations is within the skill of the ordinary worker as part of the process of normal optimization.

Conclusion

7. Claims 136-189 are rejected.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (571) 272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8000 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Konata M. George

Alton N. Pryor
Primary Examiner
A.U. 1616